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EXAMINER	
WEIER, ANTHONY J	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,604	WALSH ET AL.	
	Examiner	Art Unit	
	Anthony Weier	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,13-26,56-61,68-81,109 and 111-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 13-26, 56-61, 68-81, 109, and 111-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 13-26, 56-61, 68-81, 109, and 111-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 56, and 109, it is not clear if the percentages cited therein refer to the final textured whey protein product or whether they refer to the composition prepared prior to the thermoplastic extrusion. The instant claims call for a product "comprising a thermoplastic extrusion product *of a composition* comprising about 1-80%....protein..." (see claim 1). In addition, as a result of amendment providing that the food grade protein comprises an "undenatured" whey protein (see claims 1 and 56), it is not clear whether or not this is undenatured prior to the extrusion step or as a result of same.

Claims 111-114 are indefinite in that same are dependent on cancelled claim 110. Nevertheless, same have been examined below as though they were dependent on claim 109.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 13-16, 56-59, 68-71, 109 and 111-113 are rejected under 35 U.S.C. 102(b) as being anticipated by Morimoto et al.

Morimoto et al discloses a texturized protein product comprising a thermoplastic extruded product of a mixture comprising a dried heat-coagulable protein (e.g. milk whey, inherently food-grade and undenatured, at least until heat treated) and starch (e.g. cornstarch). It should be noted that the mixture, prior to the addition of water (see step (c) in claim 1) may consist of, as one alternative, only said heat coagulable protein (e.g. whey protein, see 100% reference in step (a) of claim 1) and as high as 30% starch and a "minor amount" of a metal sulfate (described elsewhere in the specification as being less than 2.5%, e.g. col. 3). Taking into account the amount of starch and metal sulfate (roughly 30-32.5%), the amount of said 100% heat coagulable protein of the dry mixture of step (c) would be 70 to 67.5% which falls within the range called for in the instant claims. Morimoto et al further discloses the presence of, for example, 60% protein which falls within the range set forth in claim 2. It should be noted that Morimoto et al further discloses the presence of nonheat-coagulable animal proteins such as caseinate.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 5, 6, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al alone or in view of de Ruyter.

The claims further call for the presence of plant proteins and, in particular, wheat protein. Morimoto et al discloses the use of such plant proteins (col. 3) but as alternatives to milk whey protein. In other words, Morimoto et al does not disclose the combination of such plant proteins with milk whey protein. However, since each protein component serves the same purpose, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed same together to serve the same purpose. It is obvious to combine two component each of which is taught by the prior art for the same purpose to form a third composition for the same purpose. In re Kerkhoven 205 USPQ 1069. In the alternative, de Ruyter teaches the preparation of an extruded texturized protein product which employs both heat-coagulable animal and plant proteins. It would have been further obvious to have employed both plant and animal proteins as a matter of preference due, for example, to the particular amount of protein available, cost involved, or the particular nutritional composition desired in the final product.

7. Claims 23-26 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al.

The instant claims call for the inclusion of sweet whey. Although Morimoto et al discloses the use of whey in general, same is a notoriously well known type of whey, and it would have been obvious to one having ordinary skill in the art at the time of the

invention to have employed sweet whey as a matter of preference in view of, for example, cost and availability.

The claims further call for the whey protein to be in concentrate or isolate form. Morimoto et al discloses the use of whey protein in general but provides no specifics as to the degree of purity of same. Such forms for protein are notoriously well known, and it would have been further obvious to have incorporated either form as a matter of preference depending on, for example, the particular protein form that is available.

8. Claims 1-6, 13-16, 23-26, 56-61, 68-71, 77-81, 109, 111-113, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldbrugge et al.

Feldbrugge et al discloses a texturized protein material produced by thermoplastic extrusion[1] wherein same contains whey which may be available in either concentrate or isolate form (e.g. col. 4, lines 3-21). It should be noted that Feldbrugge et al further discloses that a certain amount of the protein employed must be undenatured (see col. 3, line 64). Feldbrugge also discloses the use of wheat protein but is silent regarding the combination of, for example, wheat and whey proteins. However, since each protein component serves the same purpose, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed same together to serve the same purpose. It is obvious to combine two component each of which is taught by the prior art for the same purpose to form a third composition for the same purpose. In re Kerkhoven 205 USPQ 1069.

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[1] Morimoto et al refers to Feldbrugge et al for its thermoplastic extrusion process (see col. 1, lines 31-33).

Feldbrugge et al also discloses the inclusion of starch ingredients (col. 4, line 65) but is silent regarding the more specific use of cornstarch as claimed. However, cornstarch is notoriously well known, and, absent a showing of unexpected results, it would have been further obvious to have included same as a matter of preference depending on, for example, availability or cost.

The claims further call for particular amounts of the protein and polysaccharide components of the product. However, such determination would have been well within the purview of one having ordinary skill in the art, and it would have been obvious for said one at the time of the invention to have arrived at such amounts as a matter of preference depending on, for example, cost or availability of such ingredients.

The instant claims call for the inclusion of sweet whey. Although Feldbrugge et al discloses the use of whey in general, same is a notoriously well known type of whey, and it would have been further obvious to have employed sweet whey as a matter of preference in view of, for example, cost and availability.

9. Claims 17, 18, 72, 73, 114, and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al or Feldbrugge et al taken together with Villagran et al.

The claims further call for the inclusion of more specific polysaccharides not taught by Feldbrugge et al or Morimoto et al (e.g. pectin). However, it is known to employ such ingredients in extruded food products as taught, for example, by Villagran et al which teaches the inclusion of a variety of polysaccharide materials (carboxymethylcellulose, maltodextrin, pectin, etc.). It would have been obvious to one having ordinary skill in the art at the time of the invention to have employed such

ingredients in the product of either one of Morimoto et al or Feldbrugge et al wherein same would possess, for example, less gumminess (see Abstract).

10. Claims 19-21, 74-76, and 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al or Feldbrugge et al taken together with JP 58-28235, Yackel, Jr. et al, or Ohyabu et al.

The claims further call for the inclusion of a calcium source (e.g. calcium chloride). However, it is well known to employ calcium sources such as calcium chloride in extruded proteinaceous food products as taught, for example, by JP 58-28235. Yackel, Jr. et al teaches the use of same to toughen the texture of the extrudate, thus suggesting the use of same to provide a certain desired texture (col. 3). Ohyabu et al teaches the inclusion of calcium chloride in protein extrudates as a dehydrating agent (e.g. col. 4). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included calcium chloride in the product of either one of Feldbrugge et al or Morimoto et al for the reasons employed in JP 58-28235, Ohyabu et al, or Yackel, Jr. et al and/or, simply, for calcium fortification of a food product.

11. Claims 22, 77, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al or Feldbrugge et al taken together with Ohyabu et al.

The claims further call for the inclusion of a pH adjusting agent. Ohyabu et al teaches the treatment of protein in an acid bath to stabilize product as well as improve the heat resistance and tensile elongation of same (e.g. col. 1, line 57 - col. 2, line 15). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included such treatment to provide the benefits recited in Ohyabu et

al.

It should be noted that if it is shown that Morimoto et al and Feldbrugge et al do not provide a whey protein that is undenatured, same would be avoided due to the acid treatment as taught in Ohyabu which imparts heat resistance to the material.

Response to Arguments

12. Applicant's arguments, claim amendments, and Declaration of Conley Hansen filed 11/11/08 have been fully considered but they are not persuasive except for rejections wherein Yackel, Jr. et al was applied alone or as the primary reference of a combination.

Applicant argues that it is reasonably clear as to the composition that the ingredient percentages are related to in claims 1, 56, and 109. Examiner disagrees. In particular, it is not clear whether the percentages provided refer to the thermoplastic extrusion product or the composition employed to manufacture the thermoplastic extrusion product. Because the composition before and after extrusion would likely change in moisture content, percentages of each of the other ingredients would be affected. The recitation of "a thermoplastic extrusion product of a composition" in claim 1, for example, could refer to either the composition of the extrusion product itself or the composition used to manufacture the extrusion product.

Applicant argues that Morimoto et al requires that the protein used therein is denatured. Although this may be true, instant claims 1 and 56 both relate to textured whey protein products and make no requirement that the textured whey protein possess undenatured whey protein. Whether or not the whey protein is undenatured prior to

extrusion, the final product in Morimoto et al as well as the product of instant claims 1 and 56 will contain denatured whey protein due to the thermoplastic processing during extrusion.

Applicant argues that Morimoto et al does not disclose whey protein as a concentrate (e.g. 80% protein) and that it is not clear what Morimoto et al means by the terminology "milk-whey protein". With regard to the issue of a protein concentrate, it should be first noted that the instant claims all relate to a product wherein individual ingredients are not specified to be separate in the final product. Morimoto et al discloses a composition used to create a thermoplastic extrusion, said composition comprising at most 60% solids of which protein may be as high as 100% of said solids. Due to the presence of greater than 20% water, said composition would naturally contain a protein in essentially a concentrate form considering the presence of at least some of the water therein. Again, the claims do not require the final product to possess a separated, distinct amount of whey protein or even that a whey concentrate be present. In other words, the inclusion of water in the composition used to create the thermoplastic extrusion would inherently provide what would be tantamount to protein concentrate regardless of how same was imparted therein. As for the terminology "milk-whey protein", evidence of the meaning is provided via Feldman et al (U.S. Patent No. 3970520; also assigned to General Foods) which makes it clear that the milk-whey protein and whey protein from milk are one in the same (see claim 5).

Applicant argues that Feldbrugge et al does not employ thermoplastic extrusion and that contrary to the instant invention, Feldbrugge et al employs “simple extrusion”.

It should be noted, however, that Morimoto et al (col. 1, lines 31-33) characterizes the process of Feldbrugge et al as being one employing thermoplastic extrusion and also provides a general definition of same (col. 1, lines 19-24). The instant claims do not appear to distinguish the apparent difference in meaning between thermoplastic extrusion as contemplated by Applicant and that used in Feldbrugge (as addressed by Morimoto et al). The term "thermoplastic extrusion" has been considered broadly wherein such definition would naturally encompass the characterization of Morimoto et al. Nevertheless, it appears that Feldbrugge et al discloses an extrusion process which falls within the definition of thermoplastic extrusion set forth in Applicant's response (i.e. definition no. 4, page 28) wherein a powder-like material is pressed and heated simultaneously within a screw extruder and further wherein the material is forced through a die and cooled (inherently resulting in hardening of same). See Example 1 or Feldbrugge et al wherein the rapid cooling inherently occurs by a change in temperature of about 75 C and/or by virtue of being exposed to room temperature outside the extruding apparatus.

Applicant argues that Feldbrugge et al employs substantial shear during the extrusion process. However, the instant claims do not exclude a product formed in the manner of Feldbrugge et al wherein substantial shear is employed.

Applicant makes numerous arguments against the applied references as though same were all applied alone. However, one cannot show non-obviousness by attacking the references individually where the rejection is based on a combination of references. In re Young et al, 159 USPQ 725. Furthermore, the test for obviousness is not that the

express suggestion of the claimed invention appears in all of the references but what the references taken collectively would suggest. In re Conrad, 169 USPQ 170. Specifically, although Villagran discloses a process and product very different from that of the instant invention, same provides a teaching that would reasonably suggest to one in the art that an extruded proteinaceous product may be improved by adding polysaccharides to, for example, reduce gumminess or potential gumminess in same. JP 58282325, Yackel, Jr. et al, and Ohyabu each disclose a process and product with differences from that of the instant claimed invention but was applied for its suggestion of including a calcium source (e.g. calcium chloride) in extruded proteinaceous food products.

Applicant further argues that Morimoto teaches extrusion of protein mixed with a starch and an alkali metal sulfite. Although the instant claims do not call for the inclusion of starch and said sulfite, the instant claims claim do not exclude the presence of same.

All other arguments have been addressed in view of the rejections as set forth above.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anthony Weier

Primary Examiner
Art Unit 1761

/Anthony Weier/
Primary Examiner, Art Unit 1794

Anthony Weier
January 29, 2009